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**Dealer's Workshop                      DRAFT                      March 18 & 20, 2003**

**Purpose:**

The proposed regulations would provide for consistency with the most recently adopted federal sanitation standards, with additional rules considered by the Department as necessary to protect public health and safety for the consumption of shellfish while allowing reasonable use of the State's shellfish and whole scallops. The governing body that oversees protection of public safety is the Interstate Shellfish Sanitation Conference (ISSC), of which Maine is a member. The ISSC established the National Shellfish Sanitation Program (NSSP) rules, also referred to as the Model Ordinance. The Department's existing regulations, adopted in 1994, were in compliance with the NSSP as it existed in 1993. However, the NSSP was extensively rewritten in 1994, and again in 1998 when the ISSC incorporated Hazard Analysis and Critical Control Point (HACCP) provisions into the rules. This amendment will bring the Department's regulations up to date with the NSSP rules.

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- Bullets are **notes** indicated in **blue** for clarification.
- The section number for an existing regulation is noted in brackets [15.01].
- New text or changes proposed in accordance with the **NSSP** compared to the existing regulations are indicated in **red italics**.
- New text or changes proposed by the **Department** in addition to the NSSP are indicated in **bold plum and underlined**.
- The electronic copy is available at [www.maine.gov/dmr/](http://www.maine.gov/dmr/)

**CHAPTER 15**

**GENERAL SHELLFISH SANITATION REQUIREMENTS**

**15.01 [15.02] Compliance**

- **Changed to correctly reference District Court instead of Administrative Court.**
  - A. Each dealer shall comply with the requirements specified in Chapters 15 through 20 as appropriate to the plant and the shellfish being processed.
  - B. A violation of these regulations shall be punishable as a Class D crime, as provided by 12 M.R.S.A. §6204 and/or by license enforcement actions in District Court or by the Department. [This language should not be included in the final version of the rule - unnecessary.]

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**15.02 [15.03] Definitions**

- **Many new NSSP definitions have been added:**

- A. In addition to the definitions set forth in 1 M.R.S.A. §§71 and 72 and 12 M.R.S.A. §6001, the following definitions shall apply in interpretation of chapters 9, 10, 14 and 15-21.
1. "Adequate" means that which is needed and/or appropriate to accomplish the intended purpose and/or use in keeping with good public health practice.
  2. "Air gap" means the unobstructed vertical distance through the free atmosphere between the lowest opening from any pipe or faucet supplying water to a tank, plumbing fixture or other device and the flood level rim of the receptacle.
  3. "Approved" means a classification used to identify a growing area where harvest for direct marketing is allowed by the Department.
  4. **"Aquaculture"** for the purposes of Chapters 15 through 20 means the cultivation of shellfish seed in natural or artificial growing areas, or the cultivation of shellstock other than seed in growing areas.
  5. **"Backflow"** means the flow of water or other liquids, mixtures or substances into the distribution pipes of a potable water supply from any source or sources other than the intended source.
  6. **"Back siphonage"** means the flowing back of used, contaminated or polluted water from a plumbing fixture, vessel or other source into potable water supply pipes because of negative pressure in the water supply pipes.
  7. **"Blower"** means a receptacle for washing shucked shellfish, which uses forced air as a means of agitation.
  8. **"Bulk tagging"** means a specified written agreement between a harvester(s), a certified Maine Shellfish Dealer and the Department under which mussels, quahogs, surf clams or oysters that are harvested from one harvest area on a single day by one licensed harvester may be landed by boat bearing one tag per lot (if loose) or per pallet (if bagged, stacked and shrink wrapped). The permit applies only to transportation of shellfish from harvest area to the original certified shellfish dealer.
  9. "Certification or certify" means the issuance of a numbered certificate to a facility or vehicle for a particular activity or group of activities that indicates:
    - A. Permission from the Department to conduct the activity; and
    - B. Compliance with the requirements of state laws and regulations.

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10. "Certificate holder" means any wholesale seafood (12 M.R.S.A. §6851) or shellfish transportation (12 M.R.S.A. §6855) licensee to whom the Department has issued a certificate, as required by 12 M.R.S.A. §6856, authorizing that licensee to buy, sell, ship, transport or process shellfish. Classes of certificate holders include:
- A. Shucker-Packer (SP). The holder of a shucker-packer certificate may purchase, sell, pack, ship, shuck or transport shellfish, whether in shellstock or shucked form. A shucker-packer may not repack shucked shellfish obtained from other certificate holders. A shucker-packer shall have a facility for proper storage and/or repacking of shellstock, including a means of refrigerated storage of shellfish, i.e. a walk – in cooler.
  - B. Shellstock Shipper (SS). The holder of a shellstock shipper certificate may purchase, sell, pack, ship and transport shellstock. A shellstock shipper certificate holder may purchase and sell shucked shellfish obtained from a shucker- packer certificate holder, but must not shuck shellfish or repack shucked shellfish. A shellstock shipper shall have a facility for proper storage and packing or repacking of shellstock, including a means of refrigerated storage of shellfish, i.e. a walk-in cooler.
  - C. Reshipper (RS). The holder of a reshipper certificate may ship or transport shucked shellfish in original containers, and shellstock purchased from certified shellfish dealers to other certificate holders, retailers or to final consumers. A reshipper shall not shuck, repack, hold or store shellfish for sale, shipment or transport. A reshipper may not harvest shellfish or buy from harvesters.
  - D. Depuration Processor (DP). The holder of a depuration certificate may purchase, receive or harvest shellstock from areas classified as approved, conditionally approved, restricted or conditionally restricted and submits such shellstock to an approved depuration process. The depuration processor may pack, sell, ship or transport the depurated shellstock. A depuration processor shall have a facility, including a means of refrigerated storage of shellfish, i.e. a walk – in cooler.
  - E. A shucker-packer (A), shellstock shipper (B), or depuration processor (D) may harvest shellfish provided that individual holds a shellfish license as provided by 12 M.R.S.A. §6601.
  - F. If a shellfish certificate holder does not conduct any shellfish business activity for more than 120 days, the business shall be considered inactive. See definition 15.02(46) "inactive status".
11. **"Certificate number"** means the unique identification number issued by the Department to each dealer for each location. Each certification number shall consist of a one to five digit Arabic number preceded by the two letter state abbreviation and followed by a two letter abbreviation for the type of activity or activities the dealer is qualified to perform in accordance with the laws and regulations of the State of Maine using the following terms:
- A. Shucker - packer (SP);
  - B. Shellstock shipper (SS);
  - C. Reshipper (RS); and
  - D. Depuration processor (DP).
12. "Coliform group" means the entire aerobic and facultative anaerobic, gram-negative, nonspore forming, rod shaped bacilli, which ferment lactose broth with gas formation within 48 hours at 35 degrees centigrade.

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13. **"Commingle or Commingling"** means the act of combining different lots of shellstock or shucked shellfish.
14. **"Compliance schedule"** means a written schedule that provides a correction time period to eliminate "Key" or "Other deficiencies".
15. **"Container"** means any bag, sack, tote, conveyance or other receptacle used for containing shellfish for holding or transport.
16. **"Corrosion resistant materials"** means materials that maintain their original surface characteristics under normal exposure to the foods being contacted, normal use of cleaning compounds and bactericidal solutions, and other conditions of use.
17. **"Critical control point" (CCP)** means a point, step or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated or reduced to acceptable levels.
18. "Critical deficiency" means a condition or practice which: (a) results in the production of a product, which is unwholesome; or (b) presents a threat to the health or safety of consumers.
19. **"Critical limit"** means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate or reduce to an acceptable level the occurrence of the identified food safety hazard.
20. **"Cross connection"** means an unprotected actual or potential connection between a potable water system and any source or system containing unapproved water or a substance that is not or cannot be approved as safe and potable. Examples are bypass arrangements, jumper connection; removable sections, swivel or change over devices, or other devices through which backflow could occur.
21. **"Cull"** means to remove dead, broken or unsafe shellstock and foreign material from a lot of shellstock.
22. **"Dealer"** means a person to whom certification is issued for the activities of shellstock shipper, shucker - packer, reshipper, or depuration processor.
23. Depuration or depurate means the process of **reducing the pathogenic organisms that may be present in shellstock** by using a controlled aquatic environment as the treatment process.
24. **"Direct marketing"** means the sale for human consumption of shellfish which:
  - A. Does not require depuration or relaying prior to sale; or
  - B. Has been subjected to depuration or relaying activities.
25. **"Dry storage"** means the storage of shellstock out of water.

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- 26. “Easily cleanable”** means a surface, which is:
- A. Readily accessible; and
  - B. Is made of such materials that is so fabricated that it has a smooth finish and residues may be effectively removed by normal cleaning methods.
- 27. “Facility”** means a structure. For other connotations, use person or activity.
- 28. “Fecal coliform”** means that portion of the coliform group which will produce gas from lactose in an EC or A-1 multiple tube procedure liquid medium within 24(+2) hours in a water bath maintained at 112 °Fahrenheit (44.5 °+ 0.2 ° Centigrade).
- 29. “FDA”** means the United States Food and Drug Administration.
30. “Family shellfish operation” means shucking operations conducted under a shucker-packer certificate by immediate family members only. See definition 15.02(43) “immediate family member”.
- 31. “Food contact surface”** means an equipment surface or utensil, which normally comes into direct or indirect contact with shucked shellfish, process water or ice.
32. Food contact zone means parts of food equipment, including auxiliary equipment (such as blower pipes and drain valves), which may contact food being processed, or that drain into a portion of equipment that may contact food being processed.
- 33. “Food safety hazard”** means any biological, chemical or physical property that may cause a food to be unsafe for human consumption.
- 34. “Geometric mean”** means the antilog (base 10) of the arithmetic mean of the sample result logarithm (base 10).
- 35. “Growing area”** means any site, which supports or could support the propagation of shellstock by natural or artificial means.
- 36. “HACCP”** is an acronym that stands for Hazard Analysis Critical Control Point, a systematic, science - based approach used in food production as a means to assure food safety. The concept is built upon the seven principles identified by the National Advisory Committee on Microbiological Criteria for Foods (1992).
- 37. “HACCP Plan”** means a written document that delineates the formal procedures that a dealer follows to implement the HACCP requirements set forth in 21 Code of Federal Regulations (CFR) 123.6 as adopted by the Interstate Shellfish Sanitation Conference (ISSC).
- 38. “Harvest”** means the act of removing shellstock from growing areas and its placement on or in a manmade conveyance or other means of transport.
- 39. “Harvest area”** means an area that contains harvestable quantities of shellstock and may include aquaculture sites and facilities.
- 40. “Harvester”** means a person who **holds a current valid license that** takes shellstock by any means from a growing area.

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41. **"Heat shock"** means the process of subjecting shellstock to any form of heat treatment prior to shucking, including steam, hot water or dry heat, to facilitate removal of the meat from the shell without substantially altering the physical or organoleptic characteristics of the shellfish.
42. "Holding" means the refrigerating, storing, accumulating or processing of shellfish either shucked or in the shell, for sale, offer or transport.
43. **"Immediate family"** means mother, father, brother, sister, aunt, uncle, nephew, niece, son, daughter, grandmother and grandfather.
44. **"Importer"** means any dealer who introduces molluscan shellfish into domestic commerce. An importer has ownership of the shellfish, but need not take physical custody of the shellfish.
45. **"Includes" or "including"** means includes or including by way of illustration and not by way of limitation.
46. "Inactive Status" means a certified shellfish dealer who has not conducted any shellfish business activity for 120 days or more.
- **This definition was moved here from former Chapter 15.03(D)(6)**
47. **"Indelible"** means that which cannot be erased, blotted out, eliminated, or that which is permanent or lasting.
48. **"Inspection item"** means one of the standard criteria listed in the National Shellfish Sanitation Program (NSSP) Plant Inspection Form under which single or multiple observations of specific critical, key or other deficiencies can be debited.
49. **"Interstate Certified Shellfish Shippers List" (ICSSL)** means a FDA publication of shellfish dealers, domestic or foreign, who have been certified by a state or foreign Authority as meeting the public health control measures specified in the National Shellfish Sanitation Program (NSSP).
50. **"Interstate Shellfish Sanitation Conference" (ISSC)** means the organization which consists of agencies from shellfish producing and receiving States, FDA, the shellfish industry, the National Marine Fisheries Service of the U.S. Department of Commerce, and the U.S. Environmental Protection Agency. The ISSC provides the formal structure wherein State regulatory authorities, with FDA concurrence, can establish updated guidelines and procedures for sanitary control of the shellfish industry.
51. "Internal temperature" means the actual temperature of shellfish whether shucked or in shellstock form, as opposed to the air temperature of the container in which the shellfish is stored.
52. "Key deficiency" means a condition or practice, which may result in adulterated, decomposed, misbranded or unwholesome product.
53. **"Label"** means any written, printed or graphic matter affixed to or appearing upon any package containing shellfish.
54. **"Legible"** means that which can be read or deciphered easily.
55. "Lots":

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- A. "Shellstock": means a single type of bulk shellstock or containers of shellstock of no more than one day's harvest from a single defined growing area harvested by one or more harvesters.
  - B. "Shellstock for Depuration": means shellstock harvested from a particular area at a particular time and delivered to one depuration plant. Also the same shellstock following completion of the depuration cycle.
  - C. "Shucked Shellfish": means a lot/set of containers of no more than one day's shucked shellfish product produced under conditions as nearly uniform as possible, and designated by a common container code or marking
- 56. "Marine biotoxin"** means any poisonous compound produced by marine microorganisms and accumulated by shellstock. Examples include but are not limited to the genus *Alexandrium*.
- 57. "Monoculture"** means the culture of a single bivalve species.
- 58. "MPN" (Most Probable Number)** means a statistical estimate of the number of bacteria per unit volume and is determined from the number of positive results in a series of fermentation tubes.
59. "National Shellfish Sanitation Program" (NSSP) means the cooperative State-FDA-Industry program for the sanitary control of shellfish that is adequate to insure that the shellfish produced in accordance with the Guide for Control of Molluscan Shellfish, Revision 1999 (available at [www.ISSC.org](http://www.ISSC.org)), will be safe and sanitary.
- 60. "Operational Plan"** means a written description of the design and activities of the facility specific to, but not limited to, the species of shellfish to be processed, the source of the shellfish to be processed, how the shellfish will be processed, and how the required records will be maintained.
- 61. "Other Deficiency"** means a condition or practice that is not defined as critical or key and is not in accordance with NSSP Guide for Control of Molluscan Shellfish requirements or state regulations or laws.
- 62. "Poisonous or deleterious substance"** means a toxic substance occurring naturally or added to the environment for which a regulatory tolerance limit or action level has been established in shellfish to protect public health.
- 63. "Polyculture"** means the cultivation of:
- A. Two or more species of shellfish; or
  - B. Shellfish with other species in a common environment.
64. "Potable Water" means a water supply, which meets the requirements of the Safe Drinking Water Act, as administered by the EPA, and any applicable state or local requirements.
- 65. "Primary Dealer"** means those certified dealers who receive, purchase and/or pack shellfish directly from harvesters.
- 66. "Principal display panel"** means that part of a label that is most likely to be displayed, presented, shown or examined under customary conditions or retail sale.



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67. **Process, the verb.** The verb "process" means handling, storing, cooking, preparing, producing, manufacturing, preserving, packing or other activity which could change the condition or form. (12 MRSA §6001(35)).
68. **"Process batch"** means a quantity of shellstock used to fill each separate tank or a series of tanks supplied by a single process water system for a specified wet storage or depuration cycle in a depuration or wet storage activity.
69. **"Process water"** means the water used in a wet storage, hot dip/heat shock or depuration process.
70. **"Prohibited"** means a classification used to identify a growing area where the harvest of shellstock for any purpose, except depletion or gathering of seed for aquaculture, is not permitted.
71. **"Recall"** means an appropriate method for removing or correcting marketed consumer products, including their labeling and/or promotional literature that violate the laws administered by the Food and Drug Administration (FDA) or the Department. They are generally more efficient and afford equal and more timely consumer protection than formal administrative or civil actions, especially when the product has been widely distributed. Recalls may be undertaken at any time on the initiative of manufacturers and distributors to carry out their responsibility to protect the public health and well-being, or in response to a formal request by the Department or the US FDA.
72. "Relay means" to transfer shellstock from a growing area classified as restricted or conditionally restricted to a growing area classified as approved or conditionally approved for the purpose of reducing pathogens as measured by the coliform indicator group or poisonous or deleterious substances that may be present in the shellstock by using the ambient environment as the treatment process.
- **Conditionally restricted or approved areas and clarification of purpose have been added.**
73. **"Repacking shellstock"** means the practice of removing shellstock from containers and placing them into other containers.
74. "Restricted" means a classification used to identify a growing area where harvesting shall be by special license and the shellstock, following harvest, is subjected to a suitable and effective treatment process through relaying or depuration.
75. **"Safe materials"** means articles manufactured from or composed of materials that may not reasonably be expected to, directly or indirectly, become a component of or otherwise adversely affect the characteristics of any food.
76. **"Sanitation control record"** means records that document the monitoring of sanitation practices and conditions during processing.
77. **"Sanitize"** means to adequately treat food contact surfaces by a process that is effective in:
- A. Destroying vegetative cells of microorganisms of public health significance;
  - B. Substantially reducing the numbers of other undesirable microorganisms; and

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C. Not adversely affecting the product or its safety for the consumer.

**78. "Seed"** means shellstock, which is less than market size.

**79. "Shall"** means mandatory and required.

80. "Shellfish" means all species of:

A. Clams, mussels and oysters, whether:

(1) Shucked or in the shell;

(2) Fresh or frozen; and

(3) Whole or in part.

B. Scallops in any form, except when the final product form is the adductor muscle only.

81. "Shellstock" means live **molluscan** shellfish in the shell.

**82. "Shellstock packing"** means the process of placing shellstock into containers for introduction into commerce.

83. "Shucked Shellfish" means shellfish meats, whether whole or in part, which have been removed from the shell.

84. "Single Service Containers" means containers that are to be used only once and may not be reused. This applies to containers for shucked product, wooden shellstock crates, plastic bags and mesh bags.

85. "SPC" is "Standard Plate Count" or "Heterotrophic Plate Count" method that is used for the enumeration of total aerobic and facultative anaerobic bacteria in shellfish meat samples. The method provides a means of monitoring shellfish meats for contamination prior to and during processing. This direct quantitative technique is performed by plating shellfish bray in a pour plate assay utilizing Heterotrophic Plate Count Agar as medium. Colonies are counted on 10 plates per sample and reported as colony forming units (CFU) per 100 grams of meat. A count greater than 500,000 CFU/100 gm is unsatisfactory.

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86. **“Standardization”** means a process in which applicable staff from the FDA and the Department conduct evaluations using standard criteria in a uniform manner.
87. **“State shellfish standardized inspector”** means a person that has successfully completed the field evaluation phase of shellfish plant inspection with a state standardization officer. The state shellfish standardized inspector shall successfully complete the FDA standardization training course or one deemed acceptable by the FDA.
88. **“State shellfish standardization officer”** means a person that has successfully completed the FDA standardization training course and the field evaluation phase of shellfish plant inspection with an FDA standardization officer.
89. **“Swing deficiency”** means a deficiency noted on the NSSP Standardized Shellfish Processing Plant Inspection Form, which, depending upon the severity and circumstances can be either a “Critical” or a “Key” deficiency.
90. **“Transaction record”** means the form or forms used to document each purchase and/or sale of shellfish at the wholesale level, and includes shellfish harvest and sales records, ledgers, purchase records, invoices and bills of lading.
91. **“Wet storage”** means the temporary storage, **by a dealer**, of shellstock from **growing areas in the** approved classification **or in the open status of the conditionally approved classification** in containers or floats in natural bodies of water or in tanks containing natural or synthetic seawater.
- **“Dry storage” has been removed, see handling rules.**

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**15.03 [15.04]    Regulated Activity**

- **No change; clarifies what is lawful to possess with a permit.**
- A. Any person who purchases, possesses, processes, sells, ships, shucks, or transports shellfish in any form for other than personal use within or across State of Maine boundaries must hold a shellfish sanitation certificate from the Department, as required by 12 M.R.S.A. §6856.
  1. Exception – Common Carrier. A common carrier licensed by the Interstate Commerce Commission, as defined in §6001(8) may possess, ship or transport shellfish without a Department shellfish sanitation certificate.
  2. Exception – Retail Seafood License. The holder of a retail seafood license under §6852 may, in the retail trade within the state limits, buy, sell, transport, ship or serve shellstock or shucked shellfish without a Department certificate if the shucked shellfish are bought from a wholesale seafood license holder certified under §6856, so long as these activities are conducted at one establishment or with one vehicle.
  3. Exception – Commercial Shellfish Harvester. A commercial shellfish harvester licensed pursuant to §6601 may possess, ship or transport within the state limits or sell shellstock he has taken from open areas without a Department shellfish sanitation certificate. A licensed harvester may also shuck shellfish he has taken and sell those shucked shellfish from his home in the retail trade.
- B. [16.19 (A)(2)] It shall be unlawful for the holder of a shellfish certificate to receive, purchase, hold, wash, pack, tag or label shellstock in any location other than the permanent facility for which the holder's certificate has been issued.
  1. Exception. Certified dealers who hold a current, valid bulk tagging permit may purchase mussels and mahogany quahogs at locations other than the permanent facility for which the holder's certification was issued. Vehicles used to transport mussels and mahogany quahogs purchased at such locations must be in compliance with the requirements of Chapter 16.23.
- **This section has replaced the buyer-truck section that was not enforceable for soft shell clams being commonly transferred or held in trucks at length circumventing public health safety provisions. However, it is enforceable for the mussel and mahogany quahog industry as these species are typically packed as a final product on the harvesting vessels, ready for shipment when the vessel docks.**

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**15.04 [15.05]    Origin of Shellfish**

- **Changes include clarifications on the “areas” that shellfish may be harvested from.**

- A. It shall be unlawful to possess shellfish obtained from any source other than those listed below:
  1. Shellstock harvested by a licensed harvester from an area classified by the Department as approved, *conditionally approved in the open status, restricted in the open status, or conditionally restricted in the open status; and or*
  2. A dealer holding a shellfish certificate.
- B. [16.19 (A)(2)] In cases where a harvester is also a certified dealer, the licensee shall comply with all dealer regulations.

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**15.05 [15.09] Certification *Requirements***

- **HACCP language added. Dealers have been in compliance with the new text since December 1995. A provision has been added for dealers to provide copies of code enforcement or plumbing inspection permit. This provides a mechanism for Department inspectors to accept these types of permits to meet the NSSP requirements.**

***A. No person shall act as a dealer prior to obtaining certification.***

***B. Any person who wants to obtain certification shall:***

- 1. Apply to the Department on forms supplied by the Commissioner and shall provide all information required, including, but not limited to the following:***
  - (a) Name, address, home and business phone of the applicant as well as a list of all Department of Marine Resources licenses currently held by the applicant.***
  - (b) Exact location of the proposed facility where applicant proposes to process shellfish.***
  - (c) Detailed description of the proposed shellfish processing operation, which an applicant proposes to undertake.***
  - (d) Names of all those persons who will act as agent for the applicant, as well as the name of the manager or officer of the proposed shellfish processing facility.***
  - (e) A complete disclosure of any history of marine resource violations, whether federal or state, of the owner, agents, managers, or officers.***

***2. Have and implement a HACCP plan, and have a program of sanitation monitoring and record keeping in compliance with 21 CFR 123 as it appears in the Federal Register of December 18, 1995 and in accordance with Chapter 15.21; and***

***3. Submit local code enforcement or plumbing inspector's inspection permit to the Department to show that all plumbing and sewage within the facility meets state and local code requirements.***

***C. An operational plan shall be submitted to the Department with any application for certification, any application for a bulk tagging permit, any application for a wet storage permit and whenever there is a change in the operations of a shellfish business.***

***D. Each dealer shall have a business facility address at which inspections of facilities, activities, equipment, and records can be conducted.***

***E. Any person requesting certification shall be subject to a comprehensive onsite inspection. The state shellfish standardized inspector shall conduct the inspection, using the appropriate inspection form, within the 120-day period immediately prior to the issuance of certification.***

***F. All certifications shall expire on the last day of May each year, unless a different expiration date is specified by the Department on the certification.***

***G. Only one certification number may be issued to a dealer for a location. A person or dealer may obtain more than one certification if each business is:***

- 1. Maintained as a separate entity; and***

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***2. Is not found at the same location.***

***H. Facilities may be shared by separate certified dealers with prior written Department approval.***

I. [15.13]     The holder of a shellfish certificate shall be strictly responsible for all activities undertaken pursuant to that shellfish certificate whether or not those activities are undertaken personally by the certificate holder or by an employee, agent, manager or officer employed by the certificate holder.

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**15.06 [15.09, 15.09(C)] Certification Criteria**

- **Similar certification and inspection rules have been combined in 15.06 thru 15.10.**
  - A. The physical plant, equipment and the operations of the applicant must be in compliance with all Department regulations Chapters 16-20. The Commissioner may issue a conditional shellfish certificate to the applicant containing performance requirements for the applicant's shellfish operations.
  - B. Certification shall only be given to those applicants, which meet the following standards for certification:
    - 1. No critical deficiencies:
    - 2. Not more than 2 key deficiencies; and
    - 3. Not more than 3 other deficiencies.
  - C. The deficiencies must be corrected according to a compliance schedule approved, in writing, by the Department.

**15.07 *Renewal of Certification.***

- **This is from the NSSP; dealers have been in compliance since December 1995.**
  - A. The dealer shall apply for certification renewal annually at the time specified by the Department.***
  - B. The Department shall not certify any dealer until the dealer has:***
    - 1. Corrected any deficiencies in a compliance schedule.***
    - 2. Addressed any new key or other deficiencies in a new or revised compliance schedule; and***
      - (a) Met the requirements of Chapter 15.06(A).***



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**15.08   [15.17] Denial of Certification**

- A. Where the Commissioner determines that an applicant's proposed shellfish operations do not comply with Department regulations he/she shall deny the shellfish certificate application in writing, stating the reasons for the denial and notifying the applicant of his/her right to request an adjudicatory hearing on the denial before the Commissioner.
- B. Any applicant denied a shellfish certificate by the Commissioner may request an adjudicatory hearing before the Commissioner. The request must be in writing and must be received by the Department no later than 10 days of receipt by the applicant of the notice, by certified mail, of denial of the shellfish certificate. The Commissioner shall follow the adjudicatory hearing procedures set forth in 5 M.R.S.A. §9051 et seq. and shall give notice of the hearing as required by 5 M.R.S.A. §9052(1)(A). No public notice shall be required.
- C. Any applicant denied a shellfish certificate by the Commissioner may submit amended applications after they have corrected deficiencies cited by the Commissioner.
- D. Any applicant may request, in writing, additional Department inspections after correcting deficiencies cited in the Department inspection report.

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**15.09 [15.09(C)]                      Inspections.**

- A. Except as provided by chapter 15.10, all certified facilities must be inspected on a random basis according to the following minimum frequencies:
  - 1. All newly certified dealers will be reinspected within 30 working days.
  - 2. All shucker packers (SP) will be inspected at least once every three months.
  - 3. All shellstock shippers (SS) will be inspected at least once every six months.
  - 4. All reshippers (RS) will be inspected at least once every six months.
  - 5. All depuration plants (DP) will be inspected at least once every month.
  - 6. All wet storage permit holders will be inspected at least quarterly.
- **New DMR text: Wet storage has a higher risk for contamination that requires more frequent inspections than every 6 months, such as for shippers, but not as frequently as once a month, such as for depuration plants.**

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**15.10 Performance Based Inspection Program (PIP)**

- **New from the NSSP. This is intended to lessen the burden and reward dealers for good compliance.**
  - A. A performance based inspection program may be instituted by the Department for any dealer who meets the requirements of this section.***
  - B. The minimum frequency of inspection under a PIP shall be no less than one inspection per certification period. The certification inspection may qualify as the required minimum inspection frequency.***
  - C. To be eligible for a PIP, the dealer shall have demonstrated a history of satisfactory compliance for the previous three-year period. This demonstration shall include:***
    - 1. Full compliance with the minimum inspection frequency as provided in Chapter 15.09.***
    - 2. Certification of the dealer by the Department;***
    - 3. Verification that no critical deficiencies, no more than one key deficiency and no more than two other deficiencies have occurred in any one inspection;***
    - 4. Correction of all identified deficiencies in accordance with the compliance schedule approved by the Department; and***
    - 5. No repetition of the identified deficiencies.***

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**15.11[15.11]    Performance Bond**

Any shellfish certificate applicant adjudicated for violating any shellfish law or regulation in a civil proceeding, or convicted in a criminal proceeding for violating any shellfish law or regulation, may be required by the Commissioner to post a surety company's performance bond in the sum of Five Thousand Dollars (\$5,000.00), payable to the Treasurer State of Maine and conditioned so as to ensure faithful fulfillment of all duties and obligations imposed by law and regulation upon shellfish certificate holders. The bond must be delivered to the Commissioner prior to the reinstatement, renewal or granting of a shellfish certificate. Any subsequent judgment in a civil proceeding or conviction in a criminal proceeding shall be reported immediately to the bonding company by the Commissioner who may obtain forfeiture of the bond upon presentation of a court-certified copy of the record of the judgment or conviction.

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**15.12 [15.12] Alterations and Renovations**

- **Primarily new DMR text.** This section provides details on the requirements for the application process to make alterations or renovations. This would allow Department personnel to make an informed decision under section (C) and to insure compliance with the NSSP that requires knowledge of the physical plant (Chapter 16), handling procedures or equipment. This information is generally available from existing business plans, not new information.
- A. Prior to altering or renovating any physical plant, handling procedure or equipment, written permission must be obtained from the Commissioner.
- B. Plans must be provided to the Department at least 30 days before beginning construction for the renovation or alteration of the physical plant, and must include the following:**
  - 1. A plot plan of the entire premises showing location of:**
    - (a) All appropriate buildings and portions the layouts of these buildings: e.g. location of toilet, storage, mechanical, janitorial and garbage, etc.**
    - (b) The well, or other water source.**
    - (c) The sewage disposal system.**
    - (d) Solid waste storage equipment and location.**
  - 2. A detailed to scale drawing of the facility, showing the following:**
    - (a) Type, model and location of all equipment: e.g. equipment, shelving, counters, cupboards, etc.**
    - (b) Type, model and location of all plumbing fixtures: Prep/dishwash/hand sinks; toilets, showers, etc.**
  - 3. Construction details such as:**
    - (a) Floor construction: coved molding, surfacing material.**
    - (b) Wall and ceiling surfacing materials and finish.**
    - (c) Lighting details: type and location of fixtures.**
    - (d) Ventilation details: type and location of fixtures.**
    - (e) Plumbing schematic: hot & cold lines, waste lines, floor drains.**
  - 4. All water supply and wastewater disposal systems must comply with the requirements of the Department of Human Services and the Department of Environmental Protection with regard to drinking water and wastewater disposal, and that the construction must comply with all local fire, plumbing and electrical codes.**
- C. If the Commissioner denies permission, he/she shall issue his/her denial in writing, with specific findings to support his/her denial.

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**15.13 [15.15]    Surrender of Certificate and Reactivation of Certificate**

- A. The holder of a shellfish certificate must surrender its certificate to the Commissioner if the holder's business becomes inactive. In the event that the holder wishes to reactivate the business during the original certification period, the holder may apply in writing to the Commissioner for reissuance of the certificate. The certificate shall be reinstated by the Commissioner for the original issuance period, if the physical plant, equipment and operating procedures of the shellfish business comply with shellfish sanitation laws and regulations.
- B. Any shellfish certificate holder who relocates its shellfish processing establishment or changes vehicles used to transport shellfish shall notify the Commissioner in writing of the relocation or change and surrender the certificate issued for the former establishment or vehicle. The certificate holder shall file a new application for certification on the new establishment or vehicle.

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**15.14 [15.17] Suspension, Revocation or Refusal to Reissue a Shellfish Certificate**

- **This clarifies the existing language on what steps must be taken to close a facility for immediate public health threat.**
  - A. Suspension or Revocation
- **Actions by the Department when an inspection is refused or when there is a violation of a regulation:**
  1. The Commissioner may apply to the District Court for suspension of a shellfish certificate where the holder of such certificate has refused to allow a shellfish inspection or has violated a shellfish sanitation regulation. As provided by 12 M.R.S.A. §6373, the Commissioner may apply for suspension in a summary action before the district court pursuant to the provisions of 4 M.R.S.A. § 184.
- **Actions by the Department when there has been a conviction of Marine Resources law:**
  2. The Commissioner may suspend a shellfish certificate under 12 M.R.S.A. §6401 where the holder has been convicted of a violation of a marine resources law. The Commissioner shall follow the procedures set forth in 12 M.R.S.A. §§6351 to 6353 to impose such a suspension.
- **Actions by the Department when there is an immediate threat to public health (an immediate suspension administratively that within 30 days may be followed by 4 M.R.S.A. §184):**
  - B. [15.09(C)(2)(a)(3)] When the Department determines that a condition exists that presents an immediate threat to public health the Department may take any or all of the following actions to protect the public health:
    1. Suspend the shellfish certification in accordance with Title 5 §10004 (3 & 4);
    2. Require the holder of the shellfish certificate to initiate a recall, in accordance with Chapter 15.36, of any distributed shellfish that are adulterated or may have become adulterated; and
    3. Embargo and destroy any undistributed lots of shellfish that are adulterated or may have become adulterated in accordance with the provisions of Chapter 15.23.
- **Actions by the Department when there is non-compliance:**
  - C. [15.17(C)] If the Commissioner determines that an applicant for renewal of a shellfish certificate is not currently in compliance with shellfish sanitation regulations, or has failed to comply with shellfish sanitation regulations during the previous license period, the Commissioner may refuse renewal of the license in accordance with the following procedures:
    1. The Commissioner shall advise the applicant for renewal by certified mail, return receipt requested, of the refusal and the grounds for this refusal.
    2. The Commissioner shall advise the applicant for renewal that the applicant has a right to request that an adjudicatory hearing be held before the Department in conformity with 5 M.R.S.A., Chapter 375 subchapter IV. The Commissioner shall advise the applicant that the hearing must be requested in writing and that the written request must be received by the Department no later than 10 days of receipt by the applicant of the notice, by certified mail, of refusal to renew the shellfish certificate.
    3. If an adjudicatory hearing is requested, the Commissioner shall schedule a hearing with 10 days of the Department's receipt of the written request for hearing, unless a longer period is mutually agreed to in writing.
    4. Notice of the hearing date, time and location shall be given immediately to the applicant.

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**15.15 [15.06] Shellfish Bacterial Standards**

- **This section is existing language that has been clarified and consolidated;**
- A. It shall be unlawful to buy, sell, possess, ship, transport, transfer, shuck or otherwise process shellfish in any form unless the shellfish contain less than or equal to 230 Most Probable Number (MPN) fecal coliform per 100 grams of shellfish meat and unless the shellfish contain less than 500,000 colonies/gram Standard Plate Count (SPC).
  1. Exception. The holder of a depuration certificate or a relay permit from the Department of Marine Resources may buy, ship, transfer or transport shellfish exceeding the 230 MPN fecal coliform bacteria level when these shellfish have been harvested from an area classified as restricted or conditionally restricted in accordance with permit conditions.
- B. The Department will collect samples of shucked shellfish and shellstock from each shellfish certificate holder periodically to determine that all shellfish meet the shellfish sanitation bacterial standards, listed in Chapter 15.15(A) above.

**15.16 [15.07] Shellfish Contamination Standards - Biotoxins**

- The Department has added new language on toxins.
- A. It shall be unlawful to buy, receive, sell, possess, ship, transport, shuck or otherwise process shellfish in any form, regardless of origin where the shellfish meet the following action levels established by the NSSP "Guide for the Control of Molluscan Shellfish."
  1. For paralytic shellfish poisoning (PSP), the toxin concentration equals or exceeds 80 ug/100 mg of edible portion of raw shellfish;
  2. For neurotoxic shellfish poisoning (NSP), the harvesting of shellstock shall not be allowed when:
    - (a) Any NSP toxin is found in shellfish meats; or
    - (b) The cell counts for *Gymnodinium breve* organisms in the water column exceed 5,000 per liter;
  3. For Domoic acid, Amnesic shellfish poisoning (ASP), the toxin concentration equals or exceeds 20 ppm in the edible portion of raw shellfish; or
  4. For any marine biotoxin-producing organism for which criteria have not been established under the NSSP "Guide for the Control of Molluscan Shellfish", either cell counts in the water column or biotoxin meat concentrations may be used by the Department as the criteria for not allowing the harvest of shellstock.
- B. The Department shall collect samples of shucked shellfish and shellstock from each shellfish certificate holder periodically to determine if shellfish meet the contamination standards, described in Chapter 15.16(A) above.

**15.17 [15.06(B)] Shellfish Contamination Standards – Imported**

The Department shall collect samples of shellfish shipped or transported into this state by shellfish dealers from other states or countries to determine if those shellfish comply with the



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contamination standards described in Chapters 15.15 and 15.16 for bacterial standards and biotoxins.

**15.18 [15.08, 17.02(C) Containers & former Chapter 48 tagging]                      Shellfish Tagging and Labeling Requirements**

- **All existing dealer tagging and label requirements have been consolidated into this section with some revisions to match the NSSP. Similar harvester tagging requirements in Chapter 48 will be moved to a new Chapter 9 that applies to harvester rules.**
  - A. All shellfish shipped, transported or trans-shipped into, out of, or within the state of Maine must be transported or shipped directly from a shellfish dealer who has been certified in accordance with the provisions of the National Shellfish Sanitation Program in his state or nation of residency, and/or who is listed as a certified shellfish shipper by the Food and Drug Administration's *Interstate Certified Shellfish Shipper's List*.
  - B. It shall be unlawful to ship or transport shellfish unless the container of such shellfish bears, at all times, a waterproof label or tag as described below.
    - 1. Each container of shellstock shall bear a harvester's and/or dealer's tag which is waterproof, durable and sanctioned by the Department prior to use and is at least 2  $\frac{5}{8}$  inches x 5  $\frac{1}{4}$  inches (6.7 x 13.3 cm) in size and contains the following indelible, legible printed information in the order specified below:
      - (a) The dealer's tag shall contain:
        - (i) The dealer's name, and address;
        - (ii) The dealer's certification number assigned by the Department
      - (b) The original shipper's certification number including the state abbreviation;
      - (c) Date of harvest;
      - (d) The most precise identification of harvest location or aquaculture lease site as is practicable, including the initials of the state of Maine (ME), and the appropriate geographical location, e.g. flat or cove, river or bay, town, state. **For example: White's Cove, Nonesuch River, Shellfishville, ME.**
      - (e) Type and quantity of shellstock;
- **New section (f) added by the Department to clearly identify product for tracking purposes:**
  - (f) **When the shellstock has been placed in wet storage and it originated from a state other than Maine, the following statement: "THIS PRODUCT IS A PRODUCT OF (NAME OF STATE) AND WAS WET STORED AT (FACILITY CERTIFICATION NUMBER\*) FROM (DATE) TO (DATE)".**
  - (g) When the shellstock has been placed in wet storage and it originated from Maine, the following statement: "THIS PRODUCT WAS WET STORED AT (FACILITY CERTIFICATION NUMBER\*) FROM (DATE) TO (DATE)".

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(h) The following statement must appear in bold capitalized type "THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS".

- **Text added from NSSP in (i), (j), B and C:**

- (i) When both the dealer and harvester tags appear on the container, the dealer's tag is not required to duplicate the information on the harvester's tag.*

- (j) The following consumer advisory statement from §3-603.11 of the 1997 Food Code: "RETAILERS, INFORM YOUR CUSTOMERS" "Thoroughly cooking foods of animal origin such as beef, eggs, fish, lamb, poultry, or shellfish reduces the risk of foodborne illness. Individuals with certain health conditions may be at higher risk if these foods are consumed raw or undercooked. Consult your physician or public health official for further information."*

*B. In the instance where a certified dealer is also the harvester; the dealer's tag may also be used as the harvester's tag.*

*C. It shall be unlawful for any person or persons other than the certified dealer to be in possession of certified dealer tags.*

D. It shall be unlawful for the holder of a Maine shellfish certificate to receive, handle, buy, possess, sell, ship or transport shellfish unless each container of shellfish bears a label or tag as required by this section, Chapter 15.18.

E. The absence of labels or tags as required by this regulation shall be prima facie evidence of violation of these regulations. The absence of required labels or tags shall be grounds for the immediate embargo and destruction of the untagged or unlabeled shellfish, in that the uncertain origin of the shellfish necessarily indicates that the shellfish are of uncertain quality, and therefore, unsafe.

F. Shellfish tags that do not contain the required information or are altered or mislabeled shall be grounds for immediate embargo and destruction as being of unsound or unknown quality, and therefore, unsafe.

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**15.19 Bulk Tagging of Shellstock During Transport from Harvest Area to the Dealer Facility.**

- This section is from the NSSP and will continue to be a permitted activity as previously handled by the Department.
- A. If receiving bulk shellfish, the certified Maine shellfish dealer must have a Bulk Tagging Plan approved by the Department to ensure that each lot of shellstock is kept separate and identified in a way which prevents commingling or misidentification. The Bulk Tagging Plan must be pre-approved by the Department and must describe the standard operating procedure implemented by the dealer for handling bulk tagged product, during transportation of the product and during processing or repackaging.*
- B. When the shellstock is received from harvesters with a bulk tag and are removed from the original container, the dealer shall maintain the lot identity of all shellstock during any intermediate stage of processing under the provisions of Chapter 15.23.*

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**15.20 Tagging of Shellstock During Intermediate Processing**

- This section is from the NSSP. It describes the process to maintain shellfish "lot" integrity.

**A. When the shellstock is removed from the original container, the dealer shall:**

- 1. Maintain purchase and sales records under the provisions of Chapter 15.24;**
- 2. Maintain the lot identity of all shellstock during any intermediate stage of processing, i.e. washing and/or packing shellstock; and**
- 3. Have a written intermediate processing plan approved by the Department, which establishes procedures, the dealer shall use to tag the lot during the washing and packing of shellfish and which includes a Department approved commingling plan to ensure that each lot of shellstock is separated and identified in a way which prevents commingling or misidentification.**

**B. The identification shall be provided by:**

- 1. The harvester tag, bulk tag or dealer tag which meet the requirements of Chapter 15.18; or**
- 2. A tag for each lot of shellstock, which contains the following information:**
  - (a) A statement that "All shellstock containers in this lot have the same harvest date and area of harvest";**
  - (b) Harvest date;**
  - (c) Growing area;**
  - (d) Original dealer certification number; and**
  - (e) Number of individual containers in each lot of shellstock container (e.g. a pallet) after washing or packing has been completed.**

**C. When a dealer has an approved intermediate processing plan, the dealer shall tag each lot of shellstock in accordance with the intermediate processing plan while the lot of shellstock is being processed in the plant.**

**D. A dealer receiving bulk tagged shellstock must have an intermediate processing plan approved by the Department which establishes the procedures the dealer shall use to tag the lot during washing, packing, or staging of shellfish to ensure that each lot of shellstock is kept separate and identified in a way which prevents commingling or misidentification under the provisions of Chapter 15.19.**

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**15.21 [17.02, 15.08]      Shucked Shellfish Labeling**

- **Contains new text from the NSSP:**

- A. Each individual package containing fresh **or frozen** shucked shellfish meat shall bear a permanent printed label approved by the Department that is legibly and indelibly marked in accordance **with applicable federal and state regulations to contain, but not be limited to, the following:**
1. The packer's, distributor's and original shucker's name and address
  2. The packer's, distributor's and original shucker's certification number
  3. The type and quantity of shucked shellfish in the container
- B. The dealer shall also label each individual package containing 64 fluid ounces (1873 ml) or less of fresh or frozen shellfish with the following:**
- 1. The shucker-packer's certification number; and**
  - 2. A "SELL BY DATE" which provides a reasonable subsequent shelf life or the words "BEST IF USED BY" followed by a date when the product would be expected to reach the end of its shelf life. The date shall consist of the abbreviation for the month and number of the day of the month. For frozen shellfish, the year shall be added to the date.**
- C. The dealer shall label each individual package **containing 64 fluid ounces (1873 ml) or more** with the words "DATE SHUCKED" on both the lid and sidewall or bottom of the container. The DATE SHUCKED shall:
- 1. For fresh shellfish, consist of the number of the day of the year or the abbreviation of the month and the number of the day of the month**
  - 2. For frozen shellfish, include the year.**
- D. A dealer who freezes shucked shellfish shall label all frozen shellfish as frozen in type of equal prominence immediately adjacent to the name of the shellfish.**
- E Shellfish that has been frozen and is thawed must be labeled as previously frozen in type of equal prominence immediately adjacent to the name of the shellfish.**
- F. If a dealer uses a master shipping container, and the master container is labeled or tagged, each individual retail package of shellfish meats or shellstock within the master container need not bear a label or tag as described above.**

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**15.22 Brokers**

- **New text from the NSSP:**

*Any person acting as an independent contractor who ships or transports shellfish and who does not buy or take ownership of the shellfish being transported shall not be required to affix his/her own tag or label. However, all shellfish transported must be tagged with the name of the consignor and consignee, and the consignor or other owner of the shellfish shall remain liable for the quality of the shellfish being transported and its conformity with these regulations.*

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**15.23 [15.16]    Embargo Procedure for Shellfish**

- A. In the event that the Commissioner or his agent determines that shellfish should be embargoed, whether for violation of shellfish sanitation regulations or for any other reason set forth in 12 M.R.S.A. §6856(6), the shellfish shall be tagged with a "HOLD" label and shall not be sold, shipped, transported, moved or otherwise altered by any person, without the express permission of the Commissioner or his agent.
- B. A "HOLD" label shall be affixed to every single container or lot of shellfish subjected to embargo. The "HOLD" label shall bear a number, signifying the identity of the container or lot of embargoed shellfish. The Commissioner shall maintain a list of all current "HOLD" as well as a list of the name and address of the shellfish owner, and the reason for embargo. A copy of this information shall be given to the owner of the embargoed shellfish.
- C. It shall be unlawful to pack shellfish, whether shucked or in shellstock form into mislabeled containers, or to possess mislabeled shellfish. Shellfish shall be considered mislabeled if:
  - 1. The label is absent, bears inaccurate information, or is missing information concerning the identity of the packer, shipper, distributor, the area name, the date of harvest, the date of packing or the type and quantity of shellfish in the container.

- **Clarification added for enforcement purposes:**

**D. Shellfish that are mislabeled shall be grounds for immediate embargo and destruction as being of unsound or unknown quality, and therefore, unsafe.**

- E. [15.07(C)]            When shellfish samples indicate that those shellfish contain bacteria or toxin levels exceeding those described in Chapter 15.16 and 15.17 or the shellfish are suspected of being contaminated or of unsound quality or deleterious to the public health, the Commissioner shall embargo the contaminated shellfish, as well as any other shellfish which are likely to be contaminated in the same vehicle or facility, in accordance with the embargo powers granted to the to the Commissioner of Marine Resources in 12 M.R.S.A. §6856(6).

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**15.24 [16.22]    Shipping Documents and Records**

- Sections (A)(1)(a-c) are from the NSSP. Sub sections d & e are Department language added for the purpose of food born illness investigations:

***A. Shipping documents shall accompany each shellfish shipment and be available to the Department upon request.***

***1. The shipping documents shall contain;***

***(a) The name, address, and certification number of the shipping dealer;***

***(b) The name(s) and address (es) of the consignee(s);***

***(c) The type and quantity of the shellfish product (s) ;and***

***(d) For shellstock, the harvest area(s), harvest date(s) the process date(s) and lot number(s) (if applicable), and the original dealer Certification number(s) (if different from shipping dealer); and***

***(e) For shucked product, the shuck date(s), lot number(s) (if applicable) and the Shucker-Packer certificate number(s) (if different from the shipping dealer).***

**2. The receiving dealer shall;**

**(a) Maintain in his/her files a copy of the completed shipping document; and**

**(b) Make the shipping document available to the Department upon request**

**B. Purchase and sales records shall be maintained by each certified dealer and must meet the following criteria:**

**1. Each dealer shall have a business address at which records are maintained**

**2. Records shall:**

**(a) Be complete, accurate and legible;**

**(b) Contain all of the Department's required information in a form authorized by the Department; and**

**(c) Shall be made available for Department personnel to review and copy upon request.**

**3. The records must be sufficient to document that;**

**(a) Shellfish are from an authorized source (licensed harvester or certified dealer)**

**(b) A container of shellfish can be traced back to the specific incoming lot of shellfish from which it was taken**

**(c) A lot of shucked shellfish or a lot of shellstock can be traced back to the growing area, date of harvest, and if possible, the harvester or group of harvesters.**

**4. Records shall be maintained in a permanently bound ledger book or other recording method approved by the Department**



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5. The records shall be retained:
- (a) For fresh shellfish, for a minimum of one year and
  - (b) For frozen shellfish, for at least two years or the shelf - life of the product, whichever is longer.
- **The following new Department text is considered necessary to maintain lot integrity i.e., what has been co-mingled and to help in food born illness investigations.**  
**C. Shucked shellfish logs shall be maintained by shucker packers and must be sufficient to document:**
    - 1. Date product was shucked;**
    - 2. Product lot code;**
    - 3. The harvest area and harvest date;**
    - 4. The amount of product shucked; and**
    - 5. The total amount of product produced.**
- D. [ 15.14] Every holder of a shellfish certificate issued by the Department shall report all landings data, i.e. purchases of shellfish, on forms supplied by the Commissioner. The shellfish certificate holder shall submit these forms to the Commissioner on a monthly basis. The deadline for submission of each monthly report shall be the 15<sup>th</sup> day of the following month, for example, shellfish reports for the month of January must be submitted by the certificate holder in time for the report to arrive at the Department of Marine Resources by February 15th. The shellfish certificate holder shall be in violation of these reporting requirements if the Department does not receive a monthly shellfish report from the shellfish certificate holder by the 15<sup>th</sup> day following the reporting month.

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- The following sections Chapter 15.25 – 15.31 are new from the NSSP. HACCP is a requisite per federal law for becoming certified.

**15.25    General HACCP Requirements – Hazard Analysis**

*A. Every dealer shall conduct a hazard analysis to determine the food safety hazards that are reasonably likely to occur for each kind of shellfish product processed by that dealer and to identify the preventative measures that the dealer can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during and after harvest. A food safety hazard that is reasonably likely to occur is one for which a prudent dealer would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of shellfish product being processed in the absence of those controls. In the hazard analysis, the dealer shall consider the critical control points listed in the most recent edition of the FDA's "Fish and Fisheries Products Hazards and Controls Guide", henceforth referred to as the "Guide", as well as any recommended by the Department.*

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**15.26    General HACCP Requirements – HACCP Plan**

**A.    Every dealer shall have and implement a written HACCP plan. A HACCP plan shall be specific to:**

- 1. Each location where shellfish products are processed by that dealer; and**
- 2. Each kind of shellfish product processed by the dealer. The plan may group kinds of shellfish products together, or group kinds of production methods together, if the food safety hazard, critical control points, critical limits, and procedures required to be identified and performed are identical for all shellfish products so grouped or for all production methods so grouped.**

**B.    The HACCP plan shall, at a minimum:**

- 1. List the food safety hazards that are reasonably likely to occur, as identified in accordance with Chapter 15.25(A) and that thus must be controlled for each shellfish product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:**
  - (a) Natural toxins;**
  - (b) Microbiological contamination;**
  - (c) Chemical contamination;**
  - (d) Pesticides;**
  - (e) Drug residues;**
  - (f) Unapproved use of direct or indirect food or color additives; and**
  - (g) Physical hazards;**
- 2. List the critical control points for each of the identified food safety hazards, including as appropriate:**
  - (a) Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest. At a minimum, the critical control points shall include those identified in the Guide or recommended by the Department, as applicable. As an alternative, the dealer may establish other critical control points, which the dealer can demonstrate to the Department, to provide equivalent public health protection. If the dealer can demonstrate to the Department through a hazard analysis that the food safety hazard is not reasonably likely to occur, the critical control point is not required with the exception of receiving, which shall always be considered a critical control point.**
  - (b) Critical control points are designed to control food safety hazards that could be introduced in the processing plant environment. As an alternative, the dealer may establish other critical control points, which the dealer can demonstrate to the Department to provide equivalent public health protection. If the dealer can demonstrate to the Department through a hazard analysis that the food safety hazard is not reasonably likely to occur, the critical control point is not required. At a minimum, the critical control points shall include those identified in the Guide or as recommended by the Department, as applicable.**
- 3. List the critical limits that must be met at each of the critical control points. At a minimum, the critical limits shall include those listed in the Guide or as recommended by the Department, as applicable. As an alternative the dealer may establish other**

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*critical limits which the dealer has demonstrated provide equivalent public health protection, with the exception of receiving, which shall always be considered a critical control point. In any case, the critical limits identified in the Guide, or as recommended by the Department, shall be met as components of good manufacturing practices.*

- 4. List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits.*
  - 5. Include any corrective action plans that have been developed in accordance with Chapter 15.27, to be followed in response to deviations from critical limits at critical control points.*
  - 6. Provide for a record keeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.*
  - 7. List the verification procedures, and frequency thereof, that the dealer will use in accordance with Chapter 15.28.*
- D. The HACCP plan shall be signed and dated, either by the most responsible individual on site at the processing facility or by a higher-level official of the dealer. This signature shall signify that the dealer has accepted the HACCP plan for implementation.*
- 1. The HACCP plan shall be signed and dated:*
    - (a) Upon initial acceptance;*
    - (b) Upon any modification; and*
    - (c) Upon verification of the plan in accordance with Chapter 15.28.*

*Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with Chapter 15.31, they need not be included in the HACCP plan, and vice versa.*

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**15.27    General HACCP Requirements – Corrective Actions**

- A.   *Whenever a deviation from a critical limit occurs, a dealer shall take corrective action either by:***
- 1.   *Following a corrective action plan that is appropriated for the particular deviation, or***
  - 2.   *Following the procedures in Chapter 15.27(C).***
- B.   *Dealers may develop written corrective action plans, which become part of their HACCP plans in accordance with Chapter 15.26(B)(5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:***
- 1.   *No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and***
  - 2.   *The cause of the deviation is corrected.***
- C.   *When a deviation from a critical limit occurs and the dealer does not have a corrective action plan that is appropriate for that deviation, the dealer shall:***
- 1.   *Segregate and hold the affected product, at least until the requirements of Chapter 15.27(B)(1) and (2) are met;***
  - 2.   *Perform or obtain a review to determine the acceptability of the affected product for distribution. An individual or individuals who have adequate training or experience to perform such a review shall perform the review. Adequate training may or may not include training in accordance with Chapter 15.30;.***
  - 3.   *Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;***
  - 4.   *Take corrective action, when necessary, to correct the cause of the deviation; and***
  - 5.   *Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with Chapter 15.30, to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.***
- D.   *All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with Chapter 15.28 and the record keeping requirements of Chapter 15.29.***

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**15.28    General HACCP Requirements - Verification**

- A.    Every processor shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. Verification shall include, at a minimum:**
- 1.    A reassessment of the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way. . These changes may include: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product.**
  - 2.    An individual or individuals who have been trained in accordance with Chapter 15.30 shall perform the reassessment.**
- B.    The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of Chapter 15.26(B).**
- C.    Ongoing verification activities shall include:**
- 1.    A review of any consumer complaints that have been received by the dealer to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;**
  - 2.    The calibration of process-monitoring instruments; and**
  - 3.    At the option of the dealer, the performing of periodic end product or in-process testing.**
- D.    A review, including signing and dating, shall occur within one (1) week of the day that the records are made, by an individual who has been trained in accordance with Chapter 15.30, of the records that document:**
- 1.    The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits;**
  - 2.    The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with Chapter 15.27; and**
  - 3.    The calibrating of any process monitoring instruments used at critical control points and the performing of any periodic end product or in process testing that is part of the dealer's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures.**
- E.    Dealers shall immediately follow the procedures in Chapter 15.27 whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.**
- F.    The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing in accordance with Chapter 15.28 shall be documented in records that are subject to the records keeping requirements of Chapter 15.29.**

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**15.29    *General HACCP Requirements - HACCP and Sanitation Standard Operating Procedures (SSOP's) Records.***

- A. All records required by monitoring HACCP and SSOP's shall include:***
- 1. The name and location of the dealer;***
  - 2. The date and time of the activity that the record reflects;***
  - 3. The signature or initials of the person performing the operation; and***
  - 4. Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on the records at the time that it is observed.***
- B. All records required by monitoring HACCP and SSOP's shall be retained at the processing facility for at least one (1) year after the date they were prepared in the case of refrigerated products and for at least two (2) years after the date they were prepared in the case of frozen products.***
- C. Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility for at least two (2) years after their applicability to the product being produced at the facility.***
- D. If the processing facility is closed for a prolonged period between seasonal operations, the records may be transferred to some other reasonably accessible location at the end of the seasonal operations but shall be immediately returned for official review upon request.***
- E. The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and electronic signatures.***

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**15.30    General HACCP Requirements - Training**

- A. At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to shellfish processing at least equivalent to that received under standardized curriculum recognized as adequate by the FDA or who is otherwise qualified through job experience to perform these functions:***
  - 1. Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan that is appropriate for a specific processor, in order to meet the requirements of Chapter 15.26;***
  - 2. Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in Chapter 15.27 and the HACCP plan in accordance with the verification activities specified in Chapter 15.28; and***
  - 3. Performing the record review required by Chapter 15.29.***
- B. Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum as determined by the Department.***
- C. The trained individual need not be an employee of the dealer.***



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**15.31    *General Sanitation Requirements and Monitoring.***

- A.   *Each dealer shall monitor conditions and practices that are both appropriate to the plant and the food being processed with sufficient frequency to ensure, at a minimum, conformity with the requirements specified in Chapter 16. The requirements specified in these Sections relate to the following sanitation items:***
- 1.   *Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice, hereinafter referred to as: Safety of water for processing and ice production;***
  - 2.   *Condition and cleanliness of food contact surfaces, including    utensils, gloves, and outer garments, and from raw product to cooked product, hereinafter referred to as: Condition and cleanliness of food contact surfaces;***
  - 3.   *Prevention of cross contamination from unsanitary objects to food, food packaging materials, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product, hereinafter referred to as: Prevention of cross contamination;***
  - 4.   *Maintenance of hand washing, hand sanitizing, and toilet facilities, hereinafter referred to as: Maintenance of hand washing, hand sanitizing and toilet facilities;***
  - 5.   *Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants, hereinafter referred to as: Protection from adulterants;***
  - 6.   *Proper labeling, storage, and use of toxic compounds, hereinafter referred to as: Proper labeling, storage, and use of toxic compounds;***
  - 7.   *Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces, hereinafter referred to as: Control of employees with adverse health conditions; and***
  - 8.   *Exclusion of pests from the food plant hereinafter referred to as: Exclusion of pests.***
- B.   *Each dealer shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by Chapter 15.29(A). These records are subject to the requirements of Chapter 15.29. While monitoring of those specified conditions and practices that are not appropriate to the plant and the food being processed is not required, compliance with such conditions and practices remains mandatory.***
- C.   *Sanitation controls may be included in the HACCP plan as required by Chapter 15.28. However, to the extent that they are monitored in accordance with Chapter 15.31 they need not be included in the HACCP plan, and vice versa.***

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- **Section 15.32 contains existing text consolidated from other sections with new language from the NSSP and the Department:**

**15.32 [16.18]    Wet Storage in Artificial Bodies of Water or Near Shore.**

- A. Any dealer choosing to practice wet storage in artificial bodies of water or in near shore waters, shall apply to the Department on an annual basis for a permit for each wet storage site or operation.

1. The written application must include:

(a) The name of the dealer (as it appears on certificate), address, telephone number and certification number included as part of a letter requesting a permit for wet storage.

(b) A map indicating the exact location (including loran/GPS coordinates) being considered for near shore storage sites and floats. Onshore facilities must submit a map indicating location of facility and source water used for wet storage.

(c) A physical description, diagram or photograph of the design of the wet storage structure or system. All plans for construction or remodeling of onshore wet storage facilities shall be reviewed and approved by the Department prior to commencing construction.

(d) Local code enforcement or plumbing inspector's inspection form to the Department to show that all new and/or remodeling of existing plumbing and sewage within the facility meets state and local requirements.

(e) A written standard operating procedure which includes:

(i) a description of the purpose for the wet storage operation (i.e. holding, conditioning, or salinization) and any species specific physiological factors that may affect design criteria.

(ii) how product is tagged or identified during wet storage and,

(iii) how product is handled and tagged when it comes out of wet storage.

2. A detailed design plan of the proposed on-shore storage facility, a complete description of the source of water to be used for wet storage and details of any water treatment systems to be used. Any water treatment systems to be used must be approved by the Department.
3. The intended purpose(s) of the wet storage operation such as holding, conditioning or salinization as well as any other species specific physiological factors that may affect design criteria.
4. The operation's plan and operating procedures.
5. Wet storage must strictly comply with any and all provisions contained in the Department's written approval.

**B. The near shore wet storage site or operation shall be evaluated quarterly.**

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- C. Prior to commencing construction, all plans for construction or remodeling of onshore wet storage facilities or operations shall be reviewed and authorized by the Department.
- D. Each onshore wet storage operation shall meet the following design, construction, and operating requirements.
  - 1. Effective barriers shall be provided to prevent entry of birds, animals and vermin into the area.
  - 2. Storage tanks and related plumbing shall be constructed of safe material that is easily cleanable;
  - 3. Tanks shall be constructed so as to be easily accessible for cleaning and inspections, to be self draining and fabricated from nontoxic, corrosion resistant materials; and
  - 4. Plumbing shall be designed and installed in compliance with the Maine Plumbing Code so that cleaning and sanitizing can be conducted on a regular schedule specified in an operating procedure so as to prevent contamination of the tank and water.
  - 5. Storage tank design, dimensions and construction are such that adequate clearance shall be maintained between shellfish and the tank bottom.
  - 6. Shellfish containers must be constructed of safe materials and have a mesh type construction, which allows free flow of water to all shellfish in the containers.
  - 7. Floors, walls and ceilings shall be constructed; and lighting, plumbing and sewage disposal systems shall be installed in compliance with appropriate sections of Chapter 16.
- **Sections E – H below is new language from the NSSP:**
  - E. Near shore wet storage sites shall meet the requirements for classification as approved or conditionally approved in the open status while shellstock is being held in storage.***
  - F. When areas classified as conditionally approved are placed in a status other than open, any shellstock in wet storage in that area shall be:***
    - 1. Subjected to relaying or depuration prior to human consumption; or***
    - 2. Held in the wet storage site until the area is returned to the open status.***
  - G. Different lots of shellstock shall not be commingled in wet storage.***
  - H. If more than one lot of shellstock is held in wet storage at one time lot identity shall be maintained.***
  - I. Shellstock held or washed in water containing any other marine organism(s) shall be grounds for immediate embargo and destruction as being of unsound or unknown quality, and therefore, unsafe for human consumption.***
- J. The near shore site evaluation shall include:
  - 1. The criteria in Chapter 15.32(D); and
  - 2. The location of the near shore storage sites and floats provided on a chart and including the loran bearings.

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- K. Each near shore wet storage operation shall meet the following design, construction and operating requirements:
1. Effective barriers shall be provided to prevent entry of birds, animals and vermin into the area.
  2. Shellfish containers shall be constructed of safe materials and have a mesh type construction which allows free flow of water to all shellfish in the containers.
- **The following new sections (3)(a)&(b) are have been added by the Department to clarify how an area would be marked:**
    3. All wet storage sites shall be marked with a device which displays the certificate number and/or wet storage permit number in letters and numbers of at least 2 inches in height in colors contrasting to the background color of the device. The perimeters of the surfaces of the device shall be marked by reflective tape.
      - (a) The signs shall be exhibited by floating device, such as a buoy, on the water surface, or on top of a stake.
      - (b) The signs shall be displayed at each corner of the wet storage area that is occupied or at the outermost corners and along the perimeter not more than 100 yards apart. In cases where the area exceeds 100 yards in distance, additional devices shall be displayed so as to clearly show the boundary line of the area. In situations where the topography of the lease area interrupts the line of sight from one sign to the next, additional signs shall be displayed so as to correct this deficiency.

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- The following section 15.33 has been updated in accordance with the NSSP:  
**15.33 [16.18] Onshore Wet Storage Water Supply Requirements.**

- A. Except for wells, the quality of the surface source water prior to treatment shall meet, at a minimum, the bacteriological standards for the restricted classification.*
- B. Any well used as source water for wet storage shall meet the requirements of Chapter 16.06.*
- C. Except when the source of the water is a growing area in the approved classification, a water supply sampling schedule shall be included in the dealer's operating procedures and water shall be tested according to the schedule.*
- D. Results of water samples and other tests to determine the suitability of the water supply shall be maintained for at least 2 years.*
- E. Disinfection or other water treatment such as the addition of salt cannot leave residues unless they are Generally Recognized as Safe (GRAS) or unless they do not interfere with the shellstock's survival, quality or activity during wet storage.*
- F. Disinfected water entering the wet storage tanks shall have no detectable levels of the coliform group as measured by a recognized multi-tube MPN test per 100ml for potable water.*
- G. When the laboratory analysis of a single sample of disinfected water entering the wet storage tanks shows any positive result for the coliform group, daily sampling shall be immediately instituted until the problem is identified and eliminated.*
- H. When the problem that is causing disinfected water to show positive results for the coliform group is eliminated, the effectiveness of the correction shall be shown on the first operating day following correction through the immediate collection, within a 24 hour period, of a set of three samples of disinfected water and one sample of the source water prior to disinfection.*
  - 1. For water that is disinfected by ultra-violet treatment, turbidity shall not exceed twenty (20) nephelometric turbidity units (NTUs) measured in accordance with Standard Methods for the Examination of Water and Wastewater, APHA.*
  - 2. The disinfection units (s) for the water supply shall be cleaned and serviced as frequently as necessary to ensure effective water treatment.*
- I. If the system is of continuous flow – through design, water from a growing area classified as:*
  - 3. Approved may be used, without disinfection, in wet storage tanks provided that the near shore water source used for supplying the system meets the approved classification bacteriological criteria at all times the Shellstock are being held in wet storage; or*
  - 4. Other than approved may be used if the source water is continuously subjected to disinfection and it is sampled daily following disinfection.*

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- J. When a source classified as other than approved is used, a study shall be required to demonstrate that the disinfection system will consistently produce water that tests negative for the coliform group under normal operating conditions. The study shall:*
- 5. Include five sets of three samples from each disinfection unit collected for five consecutive days at the outlet from the disinfection unit or at the inlet to at least one of the wet storage tanks served by the disinfection system;*
  - 6. Include one sample daily for five consecutive days from the source water prior to disinfection;*
  - 7. Use NSSP recognized methods to analyze the samples to determine coliform levels;*
  - 8. Require all samples of disinfected water to be negative for the coliform group; and*
  - 9. Be repeated if any sample of disinfected water during the study is positive for the coliform group.*
- K. Once approved for use, the water system shall be sampled daily to demonstrate that the disinfected water is negative for the coliform group.*
- L. Where multiple tank systems use a common water supply system for bivalve mollusks and other species, wet storage water shall be effectively disinfected prior to entering tanks containing bivalve mollusks.*
- M. Shellstock held or washed in water containing any other marine organism(s) shall be grounds for immediate embargo and destruction as being of unsound or unknown quality, and therefore, unsafe for human consumption.*

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- The following section 15.34 has been updated in accordance with the NSSP:

**15.34    Onshore Wet Storage Using a Recirculating Water System**

- A. A study shall be required to demonstrate that the disinfection system for the recirculating system will consistently produce water that tests negative for the coliform group under normal operating conditions. The study shall meet the requirements in Chapter 15.33.*
- B. Once approved for use, the recirculating water system shall be sampled weekly to demonstrate that the disinfected water is negative for the coliform group.*
- C. When make-up water of more than 10 percent of the water volume in the recirculating system is added from a growing area source classified as other than approved, a set of three samples of disinfected water and one sample of the source water prior to disinfection shall be collected within a 24 hour period to reaffirm the ability of the system to produce water free from the coliform group.*
- D. When ultra-violet treatment is used as the water disinfectant, each time new ultraviolet bulbs are installed a set of three samples of disinfected water and one sample of the source water prior to disinfection shall be collected within a 24 hour period to reaffirm the ability of the system to produce water free from the coliform group.*
- E. Shellstock held or washed in water containing any other marine organism(s) shall be grounds for immediate embargo and destruction as being of unsound or unknown quality, and therefore, unsafe for human consumption.*

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- In Chapter 15.35 sub sections (A), (A)(1) and (C) are new from the NSSP:

**15.35    *Wet Storage Shellstock Handling***

- A.    *Shellstock shall be thoroughly washed with water from a source authorized by the Department and culled prior to wet storage in tanks.***
  - 1.    *Exception:    Due to the adverse effects of culling on mussel physiology, culling of mussels may be done after wet storage, subject to permission from the Department.***
- B.    **[16.19 (A)(4)]**    Unless the dealer is following the Department's written commingling management plan, different lots of Shellstock shall not be commingled during wet storage in tanks.**
  - 1.    If more than one lot of shellstock is being held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.**
- C.    *Shellstock held or washed in water containing any other marine organism(s) shall be grounds for immediate embargo and destruction as being of unsound or unknown quality, and therefore, unsafe for human consumption.***

- The following section is new from the NSSP:

**15.36    *Recall Procedure***

- A.    *Certified dealers shall adopt written procedures, approved by the Department for conducting recalls based on, and complementary to, the FDA Enforcement Policy on Recalls, CFR Title 21, Chapter 1, Subchapter A, Part 7 –Enforcement Policy, Appendix B, APB – 1.***
- B.    *Certified dealers shall follow their written recall procedures to include timely notification of the Department, timely notification to the consignee(s) who received the affected product and effective removal or correction of the affected product.***